DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1160B

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-21

February 4, 1997

David T. Slick, Chairman
Command Medical Products, Inc.
15 Signal Avenue
Ormond Beach, FL 32174

Dear Mr. Slick:

During an inspection of your facility in Ormond Beach, Florida on January 24 & 27, 1997, FDA Investigator Ronald T. Weber determined that you are a contract manufacturer of gastroenterologic and urological collectors, and suction and irrigation sets, which are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that the devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. These violations include, but are not limited to the following:

1. Failure to validate significant manufacturing processes and quality assurance tests, e.g., current procedures do not include three consecutive runs using variable worst case conditions, installation qualifications and calibration controls for the Radio Frequency (RF) bag closing equipment.

2. Failure to establish and implement an adequate complaint handling program, e.g., records of investigation are not always maintained, records do not identify the individual responsible for the decision not to investigate, available records of investigations are not adequately reviewed, investigations involving human error do not

identify the individual or group responsible, and not all corrections resulting from failure complaint investigations are documented.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483, Inspectional Observations, issued to Mr. Wayne Coleman, during the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems (copy enclosed). You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions. Federal agencies are advised of the issuance of all Warning Letters about devices so they may take this information into account when considering the award of contracts. Additionally, no pending applications for premarket approval (PMAs) or export approval requests will be approved and no premarket notifications [510(k)s] will be found to be substantially equivalent for products manufactured at the facility in which the above GMP violations were found until the violations have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations, including (1) each step that has or will be taken to correct the current violations, (2) the timeframe within which the corrections will be completed, (3) the person responsible for effecting correction, and (4) any documentation indicating correction has been achieved. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Please direct your reply to Timothy J. Couzins, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, ext. #264.

Sincerely,

Douglas D. Tolen
Director
Florida District

Enclosure